2018 Current Fiscal Year Report: Nonprescription Drugs Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018
3. Committee or Subcommittee	**3b. GSA Committee No.**
Nonprescription Drugs Advisory Committee	984

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	08/27/2017	08/27/2019	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 394	11/28/1990	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 0 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 0

Meetings and Dates

No Meetings

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$0.00	$6,015.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$166,846.00	$166,936.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$2,734.00
18b(1). Travel and Per Diem to Non-Federal Members	$0.00	$0.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$41,711.00	$41,734.00
18d. Total	$208,557.00	$217,419.00

19. Federal Staff Support Years (FTE)	1.10	1.10

20a. How does the Committee accomplish its purpose?
The Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advises the Commissioner either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs.

20b. How does the Committee balance its membership?
Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of internal medicine, family practice, clinical toxicology, clinical pharmacology, pharmacy, dentistry, and related specialties. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

20c. How frequent and relevant are the Committee Meetings?
The committee did not meet during FY-18. It is expected that this committee will meet two to four times in FY-19.

20d. Why can't the advice or information this committee provides be obtained elsewhere?
Members of the committee are drawn from academia, research and/or clinical practice. Their advice and input lends credibility to regulatory decision made and helps those decisions withstand intense public scrutiny. The alternate means of obtaining this advice would involve the recruitment of large number of scientists on a full-time basis at maximum rates of compensations.

20e. Why is it necessary to close and/or partially closed committee meetings?
The committee held no closed meetings during FY-18.

21. Remarks
The committee is not required to do any reporting for FY-18. Although this committee did not meet in the first quarter of FY-18, considerable time was devoted to broadening the recruitment effort of new members, screening individuals for conflicts of interest,

maintaining associated records for these activities per the requirements of FDASIA, and streamlining paper processes within FDA. In addition, time was spent in the routine care and maintenance of the committee: the development of a financial report for this website; updating the roster and number of vacancies on our website; completing the annual ethics report; reviewing financial disclosures of current members and providing ethics training; and assisting other committees by providing experts from the Nonprescription Drugs Advisory Committee.

Designated Federal Officer

Moon Hee Veronica Choi DFO

Committee Members	Start	End	Occupation	Member Designation
Baron, Elma	06/01/2016	05/31/2020	Professor of Dermatology, University Hospitals Case Medical Center/Case Western Reserve University School of Medicine	Regular Government Employee (RGE) Member
Berlin, Roger	04/13/2016	05/21/2018	Principal, 1.618 Consulting LLC	Representative Member
Di Francesco, Lorenzo	06/01/2017	05/31/2019	Professor of Medicine, Division of General Internal Medicine & Geriatrics, Emory University School of Medicine	Special Government Employee (SGE) Member
Farber, Neil	06/01/2016	05/31/2020	Professor of Clinical Medicine, University of California, San Diego	Special Government Employee (SGE) Member
King, Tonya	06/01/2016	05/31/2020	Professor of Biostatistics, Department of Public Health Sciences, A210, The Pennsylvania State University College of Medicine	Special Government Employee (SGE) Member
Mack-Brooks, Pamel	04/04/2018	05/31/2022	Coordinator Community Health Outreach, Hospital of the University of Pennsylvania	Special Government Employee (SGE) Member
Murphy, John	06/01/2017	05/31/2018	Associate Dean, Academic Affairs andAssessment, University of Arizona College of Pharmacy	Special Government Employee (SGE) Member
Neill, Richard	06/01/2017	05/31/2021	Associate Professor of Clinical Family Medicine and Community Health, University of Pennsylvania School of Medicine	Special Government Employee (SGE) Member
Roumie, Christianne	07/24/2013	05/31/2018	Staff Physician, Veterans Affairs Tennessee Valley Healthcare System	Regular Government Employee (RGE) Member
Smith, Walter	06/01/2016	05/31/2019	Associate Dean for Assessment and Accreditation, Manchester University College of Pharmacy, Natural and Health Sciences	Special Government Employee (SGE) Member
Wu, Victor	06/01/2016	05/31/2020	Chief Medical Officer, Tennessee Division of Health Care Finance and Administration	Special Government Employee (SGE) Member

Number of Committee Members Listed: 11

Narrative Description

FDA’s strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support

public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Nonprescription Drugs Advisory Committee supports FDA's strategic priorities by reviewing and evaluating available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advises the Commissioner of Food and Drugs either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee will serve as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The Committee may also conduct peer review of agency sponsored intramural and extramural scientific biomedical programs in support of FDA’s mission and regulatory responsibilities. This support the development of safe and effective new medical technologies, and advances the status of the Agency as a science-based and science-led regulatory agency, providing global leadership in the protection of public health.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

N/A

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓

Under $100,000 ☐
$100,000 - $500,000 ☐
$500,001 - $1,000,000 ☐
$1,000,001 - $5,000,000 ☐
$5,000,001 - $10,000,000 ☐
Over $10,000,000 ☐
Cost Savings Other ☐

Cost Savings Comments
The utilization of the Non-Prescription Drugs Advisory Committee enabled the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?
17

Number of Recommendations Comments
The committee made 17 recommendations from FY-03 through FY-18.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
76%

% of Recommendations Fully Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
6%

% of Recommendations Partially Implemented Comments
The function of an advisory committee is purely advisory in nature. Although the FDA

most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

It usually does. Product approval issues are first released to the sponsor. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☐
Issued new regulation	☑
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

Action Comments

FDA approves or chooses not to approve new medical products.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

N/A

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	☑
Online Agency Web Site	☑
Online Committee Web Site	☑
Online GSA FACA Web Site	☑
Publications	☑

Other

Access Comments

N/A